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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

26416/04598

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on **October 10, 2006**

Signature

Typed or printed name

Debra L. Hale

Application Number

09/812,532

Filed

March 20, 2001

First Named Inventor

David Allen Schul

Art Unit

1617

Examiner

Abigail M. Cotton

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒

attorney or agent of record.

Registration number **50,627**☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34

Signature

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Typed or printed name

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Telephone number

October 10, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒*Total of **1** forms are submitted.

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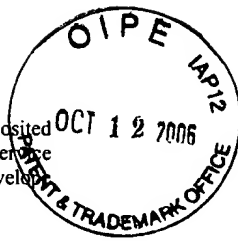
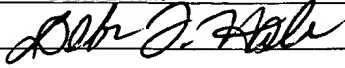
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Debra L. Hale

Signature: _____



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/812,532	Confirmation No.	2563
Applicant	:	David Allen Schul		
Filed	:	March 20, 2001		
TC/A.U.	:	1617		
Examiner	:	Abigail M. Cotton		
Docket No.	:	26416/04598		
Customer No.	:	24024		

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Alexandria, Virginia 22313-1450

REASONS FOR REQUESTING PRE-APPEAL REVIEW

Sir:

Applicants request consideration of these reason for requesting Pre-Appeal Review.

Reasons begin on page 2 of this paper.

Reasons for Requesting Pre-Appeal Review

Claims 57-63 and 65-69 are pending in this application. All claims are rejected under 35 U.S.C. § 103(a) as unpatentable over Erickson (U.S. Pat. No. 3,751,569, hereinafter referred to as “Erickson”) and Meittinen *et al.* (U.S. Pat. No. 5,502,045, hereinafter referred to as “Meittinen”) and Wester *et al.* (WO 99/56558, hereinafter referred to as “Wester”). For the reasons set forth herein, Applicants respectfully request reconsideration of claims 57-63 and 65-69.

None of the references cited, nor any combination of these references teaches or suggests an edible oil composition comprising more than 10% and up to 30% of a sterol fatty acid ester composition, wherein the sterol fatty acid ester composition comprises more than 50% monounsaturated fatty acid (MUFA) moieties; and wherein the edible oil that contains the sterol fatty acid ester composition remains clear upon addition of the sterol fatty acid ester composition as claimed by Applicants.

Miettinen is cited for showing the addition of more than 10% sterol ester to a oil. However, Applicants respectfully point out that nowhere does Miettinen teach or suggest adding more than 10% sterol ester to a **clear** oil. Miettinen shows addition of 3%, 6% and 13% sterol ester to **mayonnaise** (Example 2, columns 5-6) and addition of 10% and 20% sterol ester to a **margarine** (Example 5, column 6), but only 3% and 6% sterol ester composition to oil (Example 3). The 13% level of sterol ester added to mayonnaise (Example 2) is conspicuously missing from the example where a clear oil is made (Example 3). Applicants respectfully submit that Miettinen does not teach or suggest a **clear** edible oil containing more than 10% of a sterol fatty acid ester composition.

Erickson, cited for teaching up to 10% sterol ester composition in oil does not, in fact, overlap with Applicants’ claimed range. Erickson teaches 0.5-10% sterol ester (free sterol equivalent), which is expressly different from Applicants’ claimed percentages calculated on a sterol ester basis. (See, Applicants’ specification, page 7, lines 11-12; and Applicants’ Response of July 10, 2006, page 5, second full paragraph). The Office has not made the *prima facie* case of obviousness because it has not shown that Erickson’s ranges overlap with Applicants’.

Reasons for Requesting Pre-Appeal Review

Furthermore, Erickson does not enable one skilled in the art to make a clear edible oil containing 10% sterol ester composition. After suggesting in an offhand remark that one could make clear oils with 10% sterol oleate esters (free sterol equivalent), Erickson shows experimentally obtained solubilities for various sterol esters, with the most soluble sterol ester--the sterol oleate ester only soluble in oil at a level of 7.9%. (Erickson, column 5, Table II). Thus, while Erickson asserts that sterol esters could be added at a level of 10% (free sterol equivalent), it offers no guidance as to how this could be done. Moreover, since the Erickson shows experimentally that none of the sterol esters tested are soluble in oil at levels over 7.9%, there is no reasonable expectation of successfully preparing a clear edible oil containing more than 10% sterol ester as claimed by Applicants.

Finally, Wester does not teach or suggest a clear edible oil composition comprising more than 10% and up to 30% of a sterol fatty acid ester composition, wherein the sterol fatty acid ester composition comprises more than 50% monounsaturated fatty acid (MUFA) moieties. Wester reviews the prior art, including Erickson (Wester pages 2-3, carryover paragraph) and Miettinen (Wester, page 3, lines 17-18), then goes on to state that the problem with the prior art is the production of foods with high enough levels of phytosterols to achieve optimal effect on blood cholesterol (Wester, page 4, lines 5-9). Wester then teaches that by using more than 50% polyunsaturated fatty acid (PUFA) moieties when preparing sterol ester compositions, the sterol esters can be added to foods in sufficient quantity to achieve optimum effect. Wester thus shows two examples of prior art that used high MUFA sterol esters, which could not be used in foods in sufficient amounts for optimal effect, then shows that high PUFA sterol esters may be used in sufficient amounts in foods for optimal effects. If anything, Wester teaches away from using high MUFA sterol esters.

In conclusion, no combination of Miettinen, Erickson and Wester teach or suggest a clear edible oil containing more than 10% sterol fatty acid esters wherein the sterol fatty acid ester composition comprises more than 50% monounsaturated fatty acid (MUFA) moieties; wherein the edible oil that contains the sterol fatty acid ester composition remains clear upon addition of the sterol fatty acid ester composition; and wherein the edible oil that contains the sterol fatty acid ester composition is free of solids at temperatures of greater than about 60°F. Because no combination of Erickson, Meittinen, and Wester teach or suggest Applicants' claimed invention,

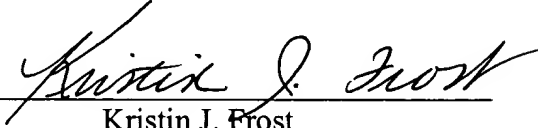
✓ Appl. No. 09/812,532

Reasons for Requesting Pre-Appeal Review

Applicants respectfully submit that claims 57-63 and 65-69 are patentable over the cited prior art. A decision to that effect is respectfully requested.

Respectfully submitted,

CALFEE, HALTER & GRISWOLD LLP

By 

Kristin J. Frost

Reg. No. 50,627